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10/563,795

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Michihiro Hide

2006-0009A

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09/05/2008

WENDEROTH, LIND & PONACK, L.L.P.

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SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/563,795 | Applicant(s) HIDE ET AL. | |
| | Examiner NORA M. ROONEY | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/10/2006 & 11/26/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 9-10 in the reply filed on 04/03/2008 is acknowledged.
2. Claims 11-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/03/2008.
3. Claim 9-10 are currently under examination as they read on a composition activating mast cell and basophils and having atopic dermatitis activity which is obtained from a human secretion.
4. Applicant's IDS documents filed on 04/10/2006 and 11/26/2007 are acknowledged.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
6. Claims 9-10 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The instant application has provided a description of a method of purifying a human sweat fraction that has the functional characteristics of being able to activate mast cells and basophils upon binding to self-IgE and being able to induce atopic dermatitis. The instant application does not disclose the biological role of the sweat fraction or its significance. The instant specification asserts specific utilities for the claimed invention for desensitization and diagnosis of atopic dermatitis.

These utilities are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for the sweat fraction. After further research, specific and substantial credible utility might be found. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

Note that the specification does not disclose the identity of the sweat fraction responsible for the disclosed utilities. As such, further research would be required to identify or research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved would be required. Since the instant specification does not disclose a credible "real world" use for the sweat fractions, then the claimed invention as disclosed does not meet the requirements of 35 U.S. C. § 101 as being useful.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9-10 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is the structure of the composition of matter. From the instant claim recitation, it is unclear what is in the recited composition comprises because the recited composition is being claimed by functional language instead of structure.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 9-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

11. Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a method for purifying human sweat; does not reasonably provide enablement for **a composition** activating mast cells and basophils upon binding to a human own

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IgE antibody and having an atopic dermatitis inducing activity, **which is obtained from a human secretion** through the following steps of: filtering a human secretion, removing insoluble matters and collecting the filtrate; mixing the filtrate with a ConA-affinity carrier and collecting the supernatant; and separating a component having an histamine-releasing activity from the supernatant by column chromatography of claim 9; and wherein the column chromatography is anion exchange column chromatography and/or reverse phase column chromatography of claim 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

The specification on pages 23-25 discloses a method of purifying human sweat.

The specification does not adequately disclose a composition obtained from a human secretion. The instant claim recitations encompass a composition comprising any human secretion for use in the claimed invention. However, any human secretion cannot be used to diagnose atopic dermatitis or activated mast cells and basophils

One of ordinary skill in the art would not be able to make an/or use the recited composition given the disclosure in the specification. Applicants have not isolated or

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characterized the fraction of sweat that is responsible for the claimed functional activities. As such, without structure, Applicants are not enabled for the composition.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

12. Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: a method for purifying human sweat.

Applicant is not in possession of: **a composition** activating mast cells and basophils upon binding to a human own IgE antibody and having an atopic dermatitis inducing activity, **which is obtained from a human secretion** through the following steps of: filtering a human secretion, removing insoluble matters and collecting the filtrate; mixing the filtrate with a ConA-affinity carrier and collecting the supernatant; and separating a component having an histamine-releasing activity from the supernatant by column chromatography of claim 9; wherein the

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column chromatography is anion exchange column chromatography and/or reverse phase column chromatography of claim 10.

Applicant has disclosed only a method for purifying human sweat; therefore, the skilled artisan cannot envision the structure of the composition recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry,

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whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hide et al. (PTO-892 mailed 03/17/2008; Reference U).

Hide et al. teaches a purified composition which is obtained from human sweat that activates mast cells and basophils upon binding to human IgE antibody and has atopic dermatitis inducing activity (In particular, abstract, 'Materials and Methods' sections, whole document).

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The recitation of "obtained from a human secretion through the following steps of: filtering a human secretion, removing insoluble matters and collecting the filtrate; mixing the filtrate with a ConA-affinity carrier and collecting the supernatant; and separating a component having an histamine-releasing activity from the supernatant by column chromatography" of claim 9; and "wherein the column chromatography is anion exchange column chromatography and/or reverse phase column chromatography" of claim 10 are included in this rejection because the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Further, once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.

The reference teachings anticipate the claimed invention.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 1, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

/Eileen B. O'Hara/

Supervisory Patent Examiner

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